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X . 510(k) Summary

Date:	December 1, 2001
Submitted By:	MicroAire® Surgical Instruments 1641 Edlich Drive Charlottesville, VA 22911
Contact Person:	Carl Angles Director of Quality and Regulatory Affairs
Telephone: Facsimile:	434-975-8000 434-975-4144
Proprietary Name: Common Name: Classification Name:	MicroAire® 1000E System Electric Surgical System for Cutting and Drilling Powered simple cranial drills, burrs, trephines and their accessories (21 CFR § 882.4310)

The MicroAire® 1000E System is substantially equivalent to the Stryker® HERMES–Ready™ Total Performance System (TPS™), 510(k) number K991696, predicate device. Although the 1000E system **does not** integrate irrigation, joint shaving and endoscopy features, the intended use, design, energy, materials, performance, safety, effectiveness, labeling, biocompatibility, and applicable standards are substantially equivalent to the Stryker TPS.

The MicroAire® 1000E System is intended for use in surgical procedures requiring the need for cutting, sawing, drilling, reaming, wire driving, pinning, screw driving, decorticating, shaping and manipulation of bone and bone related tissue.

The MicroAire® 1000E System consists of an electric power supply, power-connecting cable(s), a foot and/or hand lever power activation control, modular and unitized handpieces, modular head assemblies and accessories.

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Technological Characteristic Summary – 1000E v. TPS

Power Source: Both sources are Class I, Type BF, electrically powered and controlled devices (50-60 Hz, 100-230 VAC input), which meet the same basic voluntary safety standards (UL, CSA, IEC). However, the TPS system integrates an irrigator pump into the power console while the 1000E does not. MicroAire markets and sells a "stand-alone" irrigation system for those customers that utilize irrigation.

Electric Motors: Both systems contain modular and unitized handpieces that operate at different cycle, speed and/or torque parameters necessary for various surgical procedures.

Foot Control: Both systems utilize foot-controlling throttle mechanisms.

Electric Connecting Cable: Both systems use electric cables to connect the power supply with the handpieces.

Head Assemblies: Both systems have head configurations facilitating high, medium and low speed drills, oscillating, sagittal and reciprocating saws and wire, pinning, reaming and drilling chucks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2002

Mr. Carl Angles
Director of Quality and
Regulatory Affairs
MicroAire Surgical Instruments
1641 Edlich Drive
Charlottesville, VA 22911

Re: K014060
Trade/Device Name: MicroAire® 1000E System
Regulation Number: 882.4310, 882.4360
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Electric cranial drill motor
Regulatory Class: II
Product Code: HBE, HBC
Dated: December 7, 2001
Received: December 10, 2001

Dear Mr. Angles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K014060

Device Name: MicroAire® 1000E System

Indications For Use:

The MicroAire® 1000E System is indicated for use in cutting, sawing, drilling, reaming, wire driving, pinning, screw driving, decorticating, shaping and manipulation of bone and other bone related tissue in a variety surgical procedures. The applications include ENT, maxilliofacial, neurological, oral, orthopedic, plastic, podiatric and spinal surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

Megan C. Provost (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014060